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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,757	08/24/2001	Bettina Mockel	P 282664 000445 BT	8904
909	7590	12/16/2004	EXAMINER	
PILLSBURY WINTHROP, LLP			KERR, KATHLEEN M	
P.O. BOX 10500			ART UNIT	
MCLEAN, VA 22102			PAPER NUMBER	
			1652	

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/935,757	Applicant(s) MOCKEL ET AL.	
	Examiner Kathleen M Kerr	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9,12,15,16,18 and 21-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9,12,18,21,22 and 24-28 is/are allowed.
- 6) ☒ Claim(s) 15,16,23,29 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Application Status

1. In response to the previous Office action, a non-final rejection (mailed on March 23, 2004), Applicants filed a response and amendment received on September 23, 2004. Said amendment amended Claims 9, 12, 13, 15, 16, 18, 22-24, and 28 and added new Claims 29-30. Thus, Claims 9, 12, 13, 15, 16, 18, and 21-30 are pending in the instant Office action and will be examined herein.

Priority

2. As previously noted, the instant application is granted the benefit of priority for the foreign applications 10043336.7 and 10126422.4 filed in Germany on September 2, 2000 and May 31, 2001, respectively. Translation of said documents have been received.

As previously noted, the instant application is granted the benefit of priority for the U.S. Provisional Application No. 60/295,009 filed on June 4, 2001.

Withdrawn - Objections to the Specification

3. Previous objection to the Abstract is withdrawn by virtue of Applicant's amendment.
4. Previous objection to the amendment filed January 6, 2004 under 35 U.S.C. § 132 because it introduces new matter into the disclosure is withdrawn by virtue of Applicant's amendment to the first paragraph of the specification, removing the incorporation by reference.

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5. Previous objection to the amendment filed January 6, 2004 under 35 U.S.C. § 132 because it introduces new matter into the disclosure is withdrawn by virtue of Applicant's amendment to the specification.

Withdrawn - Claim Objections

6. Previous objection to Claim 22 under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn by virtue of Applicant's amendment rewriting Claim 22 as an independent claim.

New - Claim Objections

7. Claim 23 is objected to under 37 C.F.R. § 1.75 as being a substantial duplicate of claim 12. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See M.P.E.P. § 706.03(k).

Withdrawn - Claim Rejections - 35 U.S.C. § 112, second paragraph

8. Previous rejection of Claims 15 and 16 under 35 U.S.C. § 112, second paragraph, as being indefinite for the metes and bounds of phrases like "**the** dapA gene" (emphasis added) withdrawn by virtue of Applicant's amendment. The claims are limited to (and the language is the same in new claims 29-30) overexpressing a *C. glutamicum* dihydrodipicolinate synthase gene, for example, by increasing the copy number (inserting copies via transformation, these are extra copies if the host cell is *C. glutamicum* or these are new copies if the host cell is another

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coryneform) or operatively linked the endogenous gene to a promoter (this would apply only to methods using *C. glutamicum* host cells as these are the only ones with *C. glutamicum* genes being endogenous).

9. Previous rejection of Claims 9, 12, 13, 15, 16, 18, and 21-22 under 35 U.S.C. § 112, second paragraph, as being indefinite for the inclusion of the description of the gene as SEQ ID NO:1 AND encoding SEQ ID NO:2 is withdrawn by virtue of Applicant's amendment.

10. Previous rejection of Claims 9, 12, 13, 15, 16, 18, and 21-22 under 35 U.S.C. § 112, second paragraph, as being indefinite for what is being used to "enrich" is withdrawn by virtue of Applicant's amendment.

11. Previous rejection of Claim 15 under 35 U.S.C. § 112, second paragraph, as being indefinite for not clearly define the Markush group is withdrawn by virtue of Applicant's amendment.

New - Claim Rejections - 35 U.S.C. § 112, second paragraph

12. Claims 16 and 30 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear how a *C. glutamicum* gene can be deleted from coryneform host cells other than *C. glutamicum*. Clarification is required. The Examiner suggests limiting these claims to using *C. glutamicum* as host cells (see previous Claim 16).

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13. Claim 23 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. While the use of a vector comprising SEQ ID NO:1 is clear when the overexpression is by increasing the copy number, it is unclear how such a vector operatively links sigE to a promoter and achieves overexpression within the description of the specification. Clarification is required.

Withdrawn - Claim Rejections - 35 U.S.C. § 112, first paragraph

14. Previous rejection of Claims 9, 12, 15, 16, 18, 21-28 under 35 U.S.C. § 112, first paragraph, scope of enablement, is withdrawn by virtue of Applicant's amendment limiting the pending claims to overexpression by means of increasing the copy number or operatively linking SEQ ID NO:1 to a promoter since such examples of overexpression are enabled by the art.

Maintained - Claim Rejections - 35 U.S.C. § 112, first paragraph

15. Previous rejection of Claim 15 under 35 U.S.C. § 112, first paragraph, written description, is maintained in part; the rejection of Claim 16 is withdrawn by virtue of Applicant's deletion of the zwa2 protein limitation. The rejection of Claim 15 is withdrawn in part by virtue of Applicant's deletion of the zwa1 protein limitation; however, it is maintained for the inclusion of "a protein that exports lysine". Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons.

Applicant argues that the specification clearly describes a single species of a C. glutamicum gene that encodes a protein that exports lysine that is lysE. However, the scope of the instant limitation also encompasses any other gene encoding any other C. glutamicum lysine

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export protein. The description of a single species does not represent the genus of this broad category of proteins.

16. Previous rejection of Claim 15 under 35 U.S.C. § 112, first paragraph, scope of enablement, is maintained in part. The rejection of Claim 16 is withdrawn by virtue of Applicant's amendment removing reference to *zwa2*. The rejection of Claim 15 is withdrawn in part by Applicant's amendment removing reference to *zwa1*. The rejection of Claim 15 is maintained with respect to *lysE*. Applicant correctly inferred the typographical error in the previous Office action wherein *lysC* was cited; the correct rejection was against that of *lysE*. Applicant's arguments concerning *lysE* enablement have been fully considered but are not deemed persuasive for the following reasons. Applicant argues that *C. glutamicum lysE* is well known in the art; however, the claim is drawn to any gene encoding *C. glutamicum* lysine export protein. As previously noted, the ability to find these is not equivalent to the ability to make these as required by the statute.

Summary of Pending Issues

17. The following is a summary of the issues pending in the instant application:
- a) Claim 23 stands objected to as a duplicate claim of Claim 12.
 - b) Claims 16 and 30 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for how a *C. glutamicum* gene can be deleted from coryneform host cells other than *C. glutamicum*.
 - c) Claim 23 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the use of a vector comprising SEQ ID NO:1.
 - d) Claim 15 stands rejected under 35 U.S.C. § 112, first paragraph, written description, for any lysine export protein.
 - e) Claim 15 stands rejected under 35 U.S.C. § 112, first paragraph, scope of enablement, for methods using other lysine export proteins than those described in the specification.

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Conclusion

18. Claims 9, 12, 18, 21, 22, and 24-28 are allowed. Claims 15, 16, 23, and 29-30 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (571) 272-0931. The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kathleen M Kerr
Primary Examiner
Art Unit 1652

December 11, 2004